

108TH CONGRESS  
1ST SESSION

# H. R. 2122

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## AN ACT

To enhance research, development, procurement, and use of biomedical countermeasures to respond to public health threats affecting national security, and for other purposes.



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To enhance research, development, procurement, and use of biomedical countermeasures to respond to public health threats affecting national security, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2       This Act may be cited as the “Project BioShield Act  
3 of 2003”.

4 **SEC. 2. BIOMEDICAL COUNTERMEASURE RESEARCH AND**  
5 **DEVELOPMENT AUTHORITIES.**

6       (a) IN GENERAL.—Part B of title III of the Public  
7 Health Service Act (42 U.S.C. 243 et seq.) is amended  
8 by inserting after section 319F the following section:

9 **“SEC. 319F-1. AUTHORITY FOR USE OF CERTAIN PROCE-**  
10 **DURES REGARDING QUALIFIED COUNTER-**  
11 **MEASURE RESEARCH AND DEVELOPMENT**  
12 **ACTIVITIES.**

13       “(a) IN GENERAL.—

14               “(1) AUTHORITY.—In conducting and sup-  
15 porting research and development activities regard-  
16 ing biomedical countermeasures under section  
17 319F(h), the Secretary may conduct and support  
18 such activities in accordance with this section if the  
19 activities concern qualified countermeasures.

20               “(2) QUALIFIED COUNTERMEASURE.—For pur-  
21 poses of this section, the term ‘qualified counter-  
22 measure’ means a priority countermeasure (as de-  
23 fined in section 319F(h) and as determined by the  
24 Secretary in accordance with such section and con-  
25 sistent with sections 302(2) and 304(a) of the  
26 Homeland Security Act of 2002) against a chemical,

1 biological, radiological, or nuclear agent that may  
2 cause a public health emergency affecting national  
3 security.

4 “(3) INTERAGENCY COOPERATION.—

5 “(A) IN GENERAL.—In carrying out activi-  
6 ties under this section, the Secretary is author-  
7 ized, subject to subparagraph (B), to enter into  
8 interagency agreements and other collaborative  
9 undertakings with other agencies of the United  
10 States Government.

11 “(B) LIMITATION.—An agreement or un-  
12 dertaking under this paragraph shall not au-  
13 thorize another agency to exercise the authori-  
14 ties provided by this section.

15 “(4) AVAILABILITY OF FACILITIES TO THE SEC-  
16 RETARY.—In any grant, contract, or cooperative  
17 agreement entered into under the authority provided  
18 in this section with respect to a biocontainment lab-  
19 oratory or other related or ancillary specialized re-  
20 search facility that the Secretary determines nec-  
21 essary for the purpose of performing, administering,  
22 or supporting qualified countermeasure research and  
23 development, the Secretary may provide that the fa-  
24 cility that is the object of such grant, contract, or  
25 cooperative agreement shall be available as needed to

1 the Secretary to respond to public health emer-  
2 gencies affecting national security.

3 “(5) TRANSFERS OF QUALIFIED COUNTER-  
4 MEASURES.—Each agreement for an award of a  
5 grant, contract, or cooperative agreement under sec-  
6 tion 319F(h) for the development of a qualified  
7 countermeasure shall provide that the recipient of  
8 the award will comply with all applicable export-re-  
9 lated controls with respect to such countermeasure.

10 “(b) EXPEDITED PROCUREMENT AUTHORITY.—

11 “(1) INCREASED SIMPLIFIED ACQUISITION  
12 THRESHOLD FOR QUALIFIED COUNTERMEASURE  
13 PROCUREMENTS.—

14 “(A) IN GENERAL.—For any procurement  
15 by the Secretary of property or services for use  
16 (as determined by the Secretary) in performing,  
17 administering, or supporting qualified counter-  
18 measure research or development activities  
19 under this section that the Secretary deter-  
20 mines necessary to respond to pressing research  
21 and development needs under this section, the  
22 amount specified in section 4(11) of the Office  
23 of Federal Procurement Policy Act (41 U.S.C.  
24 403(11)), as applicable pursuant to section  
25 302A(a) of the Federal Property and Adminis-

1           trative Services Act of 1949 (41 U.S.C.  
2           252a(a)), shall be deemed to be \$25,000,000 in  
3           the administration, with respect to such pro-  
4           curement, of—

5                   “(i) section 303(g)(1)(A) of the Fed-  
6                   eral Property and Administrative Services  
7                   Act of 1949 (41 U.S.C. 253(g)(1)(A)) and  
8                   its implementing regulations; and

9                   “(ii) section 302A(b) of such Act (41  
10                  U.S.C. 252a(b)) and its implementing reg-  
11                  ulations.

12                  “(B) APPLICATION OF CERTAIN PROVI-  
13                  SIONS.—Notwithstanding subparagraph (A)  
14                  and the provision of law and regulations re-  
15                  ferred to in such subparagraph, each of the fol-  
16                  lowing provisions shall apply to procurements  
17                  described in this paragraph to the same extent  
18                  that such provisions would apply to such pro-  
19                  curements in the absence of subparagraph (A):

20                   “(i) Chapter 37 of title 40, United  
21                   States Code (relating to contract work  
22                   hours and safety standards).

23                   “(ii) Subsections (a) and (b) of sec-  
24                   tion 7 of the Anti-Kickback Act of 1986  
25                   (41 U.S.C. 57(a) and (b)).

1                   “(iii) Section 304C of the Federal  
2                   Property and Administrative Services Act  
3                   of 1949 (41 U.S.C. 254d) (relating to the  
4                   examination of contractor records).

5                   “(C) INTERNAL CONTROLS TO BE INSTI-  
6                   TUTED.—The Secretary shall institute appro-  
7                   priate internal controls for procurements that  
8                   are under this paragraph, including require-  
9                   ments with regard to documenting the justifica-  
10                  tion for use of the authority in this paragraph.

11                  “(2) PROCEDURES OTHER THAN FULL AND  
12                  OPEN COMPETITION.—

13                  “(A) IN GENERAL.—In using the authority  
14                  provided in section 303(c)(1) of title III of the  
15                  Federal Property and Administrative Services  
16                  Act of 1949 (41 U.S.C. 253(c)(1)) to use proce-  
17                  dures other than competitive procedures in the  
18                  case of a procurement described in paragraph  
19                  (1) of this subsection, the phrase ‘available  
20                  from only one responsible source’ in such sec-  
21                  tion 303(c)(1) shall be deemed to mean ‘avail-  
22                  able from only one responsible source or only  
23                  from a limited number of responsible sources’.

24                  “(B) RELATION TO OTHER AUTHORI-  
25                  TIES.—The authority under subparagraph (A)



1 is in addition to any other authority to use pro-  
2 cedures other than competitive procedures.

3 “(C) APPLICABLE GOVERNMENT-WIDE  
4 REGULATIONS.—The Secretary shall implement  
5 this paragraph in accordance with applicable  
6 government-wide regulations, including require-  
7 ments that offers be solicited from as many po-  
8 tential sources as is practicable under the cir-  
9 cumstances, that required notices be published,  
10 and that submitted offers be considered.

11 “(3) INCREASED MICROPURCHASE THRESH-  
12 OLD.—

13 “(A) IN GENERAL.—For a procurement  
14 described by paragraph (1), the amount speci-  
15 fied in subsections (c), (d), and (f) of section 32  
16 of the Office of Federal Procurement Policy Act  
17 (41 U.S.C. 428) shall be deemed to be \$15,000  
18 in the administration of that section with re-  
19 spect to such procurement.

20 “(B) INTERNAL CONTROLS TO BE INSTI-  
21 TUTED.—The Secretary shall institute appro-  
22 priate internal controls for purchases that are  
23 under this paragraph and that are greater than  
24 \$2,500.

1           “(C) EXCEPTION TO PREFERENCE FOR  
2 PURCHASE CARD MECHANISM.—No provision of  
3 law establishing a preference for using a Gov-  
4 ernment purchase card method for purchases  
5 shall apply to purchases that are under this  
6 paragraph and that are greater than \$2,500.

7           “(4) REVIEW.—

8           “(A) REVIEW ALLOWED.—Notwithstanding  
9 any other provision of law, including subsection  
10 (f), review of a contracting agency decision re-  
11 lating to a procurement described in paragraph  
12 (1) may be had only by filing a protest—

13                   “(i) with a contracting agency; or

14                   “(ii) with the Comptroller General  
15 under subchapter V of chapter 35 of title  
16 31, United States Code.

17           “(B) OVERRIDE OF STAY OF CONTRACT  
18 AWARD OR PERFORMANCE COMMITTED TO  
19 AGENCY DISCRETION.—Notwithstanding any  
20 other provision of law, the following authoriza-  
21 tions by the head of a procuring activity are  
22 committed to agency discretion:

23                   “(i) An authorization under section  
24 3553(c)(2) of title 31, United States Code,

1 to award a contract for a procurement de-  
2 scribed in paragraph (1) of this subsection.

3 “(ii) An authorization under section  
4 3553(d)(3)(C) of such title to perform a  
5 contract for a procurement described in  
6 paragraph (1) of this subsection.

7 “(c) AUTHORITY TO EXPEDITE PEER REVIEW.—

8 “(1) IN GENERAL.—The Secretary may, as the  
9 Secretary determines necessary to respond to press-  
10 ing qualified countermeasure research and develop-  
11 ment needs under this section, employ such expe-  
12 dited peer review procedures (including consultation  
13 with appropriate scientific experts) as the Secretary,  
14 in consultation with the Director of NIH, deems ap-  
15 propriate to obtain assessment of scientific and tech-  
16 nical merit and likely contribution to the field of  
17 qualified countermeasure research, in place of the  
18 peer review and advisory council review procedures  
19 that would be required under sections 301(a)(3),  
20 405(b)(1)(B), 405(b)(2), 406(a)(3)(A), 492, and  
21 494, as applicable to a grant, contract, or coopera-  
22 tive agreement—

23 “(A) that is for performing, administering,  
24 or supporting qualified countermeasure research  
25 and development activities; and

1                   “(B) the amount of which is not greater  
2                   than \$1,500,000.

3                   “(2) SUBSEQUENT PHASES OF RESEARCH.—

4                   The Secretary’s determination of whether to employ  
5                   expedited peer review with respect to subsequent  
6                   phases of a research grant, contract, or cooperative  
7                   agreement under this section shall be determined  
8                   without regard to the peer review procedures used  
9                   for any prior peer review of that same grant, con-  
10                  tract, or cooperative agreement.

11                  “(d) AUTHORITY FOR PERSONAL SERVICES CON-  
12                  TRACTS.—

13                  “(1) IN GENERAL.—For the purpose of per-  
14                  forming, administering, or supporting qualified  
15                  countermeasure research and development activities,  
16                  the Secretary may, as the Secretary determines nec-  
17                  essary to respond to pressing qualified counter-  
18                  measure research and development needs under this  
19                  section, obtain by contract (in accordance with sec-  
20                  tion 3109 of title 5, United States Code, but without  
21                  regard to the limitations in such section on the pe-  
22                  riod of service and on pay) the personal services of  
23                  experts or consultants who have scientific or other  
24                  professional qualifications, except that in no case  
25                  shall the compensation provided to any such expert

1 or consultant exceed the daily equivalent of the an-  
2 nual rate of compensation for the President.

3 “(2) FEDERAL TORT CLAIMS ACT COVERAGE.—

4 “(A) IN GENERAL.—A person carrying out  
5 a contract under paragraph (1), and an officer,  
6 employee, or governing board member of such  
7 person, shall be deemed to be an employee of  
8 the Department of Health and Human Services  
9 for purposes of claims under sections 1346(b)  
10 and 2672 of title 28, United States Code, for  
11 money damages for personal injury, including  
12 death, resulting from performance of functions  
13 under such contract.

14 “(B) EXCLUSIVITY OF REMEDY.—The  
15 remedy provided by subparagraph (A) shall be  
16 exclusive of any other civil action or proceeding  
17 by reason of the same subject matter against  
18 the person, officer, employee, or governing  
19 board member.

20 “(3) INTERNAL CONTROLS TO BE INSTI-  
21 TUTED.—

22 “(A) IN GENERAL.—The Secretary shall  
23 institute appropriate internal controls for con-  
24 tracts under this subsection, including proce-  
25 dures for the Secretary to make a determina-

tion of whether a person, or an officer, employee, or governing board member of a person, is deemed to be an employee of the Department of Health and Human Services pursuant to paragraph (2).

“(B) DETERMINATION OF EMPLOYEE STATUS TO BE FINAL.—A determination by the Secretary under subparagraph (A) that a person, or an officer, employee, or governing board member of a person, is or is not deemed to be an employee of the Department of Health and Human Services shall be final and binding on the Secretary and the Attorney General and other parties to any civil action or proceeding.

“(4) NUMBER OF PERSONAL SERVICES CONTRACTS LIMITED.—The number of experts and consultants whose personal services are obtained under paragraph (1) shall not exceed 30 at any time.

“(e) STREAMLINED PERSONNEL AUTHORITY.—

“(1) IN GENERAL.—In addition to any other personnel authorities, the Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, without regard to such provisions of title 5, United States Code, governing ap-

1 pointments in the competitive service, and without  
2 regard to the provisions of chapter 51 and sub-  
3 chapter III of chapter 53 of such title relating to  
4 classification and General Schedule pay rates, ap-  
5 point professional and technical employees, not to  
6 exceed 30 such employees at any time, to positions  
7 in the National Institutes of Health to perform, ad-  
8 minister, or support qualified countermeasure re-  
9 search and development activities in carrying out  
10 this section.

11 “(2) INTERNAL CONTROLS TO BE INSTI-  
12 TUTED.—The Secretary shall institute appropriate  
13 internal controls for appointments under this sub-  
14 section.

15 “(f) ACTIONS COMMITTED TO AGENCY DISCRE-  
16 TION.—Actions by the Secretary under the authority of  
17 this section are committed to agency discretion.”.

18 (b) TECHNICAL AMENDMENT.—Section 481A of the  
19 Public Health Service Act (42 U.S.C. 287a-2) is  
20 amended—

21 (1) in subsection (a)(1)—

22 (A) by inserting “or the Director of the  
23 National Institute of Allergy and Infectious  
24 Diseases” after “Director of the Center”; and

1 (B) by inserting “, or in the case of the In-  
2 stitute, to any qualified public or private enti-  
3 ty,” after “private entities”;

4 (2) in subsection (c)—

5 (A) in paragraph (1), by inserting “or the  
6 Director of the National Institute of Allergy  
7 and Infectious Diseases” after “Director of the  
8 Center”; and

9 (B) in paragraph (2), in the matter pre-  
10 ceeding subparagraph (A), by striking “sub-  
11 section (i)” and inserting “subsection (i)(1)”;

12 (3) in subsection (d), by inserting “or the Di-  
13 rector of the National Institute of Allergy and Infec-  
14 tious Diseases” after “Director of the Center”;

15 (4) in subsection (e)—

16 (A) in paragraph (1)—

17 (i) in the matter preceding subpara-  
18 graph (A), by inserting “or the Director of  
19 the National Institute of Allergy and Infec-  
20 tious Diseases” after “Director of the Cen-  
21 ter”;

22 (ii) in subparagraph (A), by inserting  
23 “(or, in the case of the Institute, 75 per-  
24 cent)” after “50 percent”; and



1 (iii) in subparagraph (B), by inserting  
2 “(or, in the case of the Institute, 75 per-  
3 cent)” after “40 percent”;

4 (B) in paragraph (2), by inserting “or the  
5 Director of the National Institute of Allergy  
6 and Infectious Diseases” after “Director of the  
7 Center”; and

8 (C) in paragraph (4), by inserting “of the  
9 Center or the Director of the National Institute  
10 of Allergy and Infectious Diseases” after “Di-  
11 rector”;

12 (5) in subsection (f)—

13 (A) in paragraph (1), by inserting “in the  
14 case of an award by the Director of the Cen-  
15 ter,” before “the applicant”; and

16 (B) in paragraph (2), by inserting “of the  
17 Center or the Director of the National Institute  
18 of Allergy and Infectious Diseases” after “Di-  
19 rector”; and

20 (6) in subsection (i)—

21 (A) by striking “APPROPRIATIONS.—For  
22 the purpose of carrying out this section,” and  
23 inserting the following: “APPROPRIATIONS.—

24 “(1) CENTER.—For the purpose of carrying out  
25 this section with respect to the Center,”; and

1 (B) by adding at the end the following:

2 “(2) NATIONAL INSTITUTE OF ALLERGY AND  
3 INFECTIOUS DISEASES.—For the purpose of car-  
4 rying out this section with respect to the National  
5 Institute of Allergy and Infectious Diseases, there  
6 are authorized to be appropriated such sums as may  
7 be necessary for each of the fiscal years 2003 and  
8 2004.”.

9 (c) ADDITIONAL AUTHORITY.—Section 319F of the  
10 Public Health Service Act (42 U.S.C. 247d–6) is  
11 amended—

12 (1) by redesignating subsections (i) and (j) as  
13 subsections (j) and (k), respectively; and

14 (2) by inserting after subsection (h) the fol-  
15 lowing subsection:

16 “(i) PRIORITY COUNTERMEASURES FOR STRATEGIC  
17 NATIONAL STOCKPILE.—

18 “(1) IN GENERAL.—The Secretary, taking into  
19 consideration any recommendations of the working  
20 group under subsection (a), may initiate and sustain  
21 a program that results in the delivery of priority  
22 countermeasures for placement in the stockpile  
23 under section 319F–2.

24 “(2) AUTHORIZATION OF APPROPRIATIONS.—  
25 For the purpose of carrying out paragraph (1), there

1       are authorized to be appropriated such sums as may  
2       be necessary for each of the fiscal years 2004  
3       through 2013.”.

4       (d) ADDITIONAL AUTHORIZATIONS OF APPROPRIA-  
5 TIONS.—Section 2106 of the Public Health Service Act  
6 (42 U.S.C. 300aa–6) is amended—

7           (1) in subsection (a), by striking “authorized to  
8       be appropriated” and all that follows and inserting  
9       the following: “authorized to be appropriated such  
10      sums as may be necessary for each of the fiscal  
11      years 2004 through 2013.”; and

12          (2) in subsection (b), by striking “authorized to  
13      be appropriated” and all that follows and inserting  
14      the following: “authorized to be appropriated such  
15      sums as may be necessary for each of the fiscal  
16      years 2004 through 2013.”.

17      (e) TECHNICAL AMENDMENTS.—Section 319F of the  
18 Public Health Service Act (42 U.S.C. 247d–6) is  
19 amended—

20          (1) in subsection (a), by inserting “the Sec-  
21      retary of Homeland Security,” after “Management  
22      Agency,”; and

23          (2) in subsection (h)(4)(B), by striking “to di-  
24      agnose conditions” and inserting “to treat, identify,  
25      or prevent conditions”.

1 (f) RULE OF CONSTRUCTION.—Nothing in this sec-  
 2 tion has any legal effect on sections 302(2), 302(4),  
 3 304(a), or 304(b) of the Homeland Security Act of 2002.

4 **SEC. 3. BIOMEDICAL COUNTERMEASURES PROCUREMENT.**

5 (a) ADDITIONAL AUTHORITY REGARDING STRATEGIC  
 6 NATIONAL STOCKPILE.—

7 (1) TRANSFER OF PROGRAM.—Section 121 of  
 8 the Public Health Security and Bioterrorism Pre-  
 9 paredness and Response Act of 2002 (116 Stat.  
 10 611; 42 U.S.C. 300hh–12) is transferred from such  
 11 Act to the Public Health Service Act, is redesignated  
 12 as section 319F–2, and is inserted after section  
 13 319F–1 of the Public Health Service Act (as added  
 14 by section 2 of this Act).

15 (2) ADDITIONAL AUTHORITY.—Section 319F–2  
 16 of the Public Health Service Act, as added by para-  
 17 graph (1), is amended to read as follows:

18 **“SEC. 319F–2. STRATEGIC NATIONAL STOCKPILE.**

19 **“(a) STRATEGIC NATIONAL STOCKPILE.—**

20 **“(1) IN GENERAL.—**The Secretary of Homeland  
 21 Security (referred to in this section as the ‘Home-  
 22 land Security Secretary’), in coordination with the  
 23 Secretary and the Secretary of Veterans Affairs,  
 24 shall maintain a stockpile or stockpiles of drugs, vac-  
 25 cines and other biological products, medical devices,

1 and other supplies in such numbers, types, and  
2 amounts as are determined by the Secretary to be  
3 appropriate and practicable, taking into account  
4 other available sources, to provide for the emergency  
5 health security of the United States, including the  
6 emergency health security of children and other vul-  
7 nerable populations, in the event of a bioterrorist at-  
8 tack or other public health emergency.

9 “(2) PROCEDURES.—The Secretary, in man-  
10 aging the stockpile under paragraph (1), shall—

11 “(A) consult with the working group under  
12 section 319F(a);

13 “(B) ensure that adequate procedures are  
14 followed with respect to such stockpile for in-  
15 ventory management and accounting, and for  
16 the physical security of the stockpile;

17 “(C) in consultation with Federal, State,  
18 and local officials, take into consideration the  
19 timing and location of special events;

20 “(D) review and revise, as appropriate, the  
21 contents of the stockpile on a regular basis to  
22 ensure that emerging threats, advanced tech-  
23 nologies, and new countermeasures are ade-  
24 quately considered;

1           “(E) devise plans for the effective and  
2           timely supply-chain management of the stock-  
3           pile, in consultation with appropriate Federal,  
4           State and local agencies, and the public and  
5           private health care infrastructure; and

6           “(F) ensure the adequate physical security  
7           of the stockpile.

8           “(b) SMALLPOX VACCINE DEVELOPMENT.—

9           “(1) IN GENERAL.—The Secretary shall award  
10          contracts, enter into cooperative agreements, or  
11          carry out such other activities as may reasonably be  
12          required in order to ensure that the stockpile under  
13          subsection (a) includes an amount of vaccine against  
14          smallpox as determined by such Secretary to be suf-  
15          ficient to meet the health security needs of the  
16          United States.

17          “(2) RULE OF CONSTRUCTION.—Nothing in  
18          this section shall be construed to limit the private  
19          distribution, purchase, or sale of vaccines from  
20          sources other than the stockpile described in sub-  
21          section (a).

22          “(c) ADDITIONAL AUTHORITY REGARDING PRO-  
23          CUREMENT OF CERTAIN BIOMEDICAL COUNTER-  
24          MEASURES; AVAILABILITY OF SPECIAL RESERVE  
25          FUND.—

1 “(1) IN GENERAL.—

2 “(A) USE OF FUND.—A security counter-  
3 measure may, in accordance with this sub-  
4 section, be procured with amounts in the special  
5 reserve fund under paragraph (10).

6 “(B) SECURITY COUNTERMEASURE.—For  
7 purposes of this subsection, the term ‘security  
8 countermeasure’ means a priority counter-  
9 measure (as defined in section 319F(h) and as  
10 determined by the Secretary in accordance with  
11 such section and consistent with sections  
12 302(2) and 304(a) of the Homeland Security  
13 Act of 2002) that—

14 “(i)(I) is against a chemical, biologi-  
15 cal, radiological, or nuclear agent identified  
16 as a material threat under paragraph  
17 (2)(A)(ii);

18 “(II) is determined under paragraph  
19 (2)(B)(ii) to be a necessary counter-  
20 measure; and

21 “(III)(aa) is approved or cleared  
22 under chapter V of the Federal Food,  
23 Drug, and Cosmetic Act, or licensed under  
24 section 351 of this Act, for use as a coun-  
25 termeasure to a chemical, biological, radio-

logical, or nuclear agent identified as a  
material threat under paragraph (2)(A)(ii);  
or

“(bb) is a priority countermeasure for  
which the Secretary determines that suffi-  
cient and satisfactory clinical experience or  
research data (including data, if available,  
from pre-clinical and clinical trials) sup-  
port a reasonable conclusion that the coun-  
termeasure will qualify for approval or li-  
censing after the date of a determination  
under paragraph (5); or

“(ii) is authorized under section 564  
of the Federal Food, Drug, and Cosmetic  
Act for emergency use.

“(2) DETERMINATION OF MATERIAL  
THREATS.—

“(A) MATERIAL THREAT.—The Homeland  
Security Secretary, in consultation with the  
heads of other agencies as appropriate, shall on  
an ongoing basis—

“(i) assess current and emerging  
threats of chemical, biological, radiological,  
and nuclear agents; and



1 “(ii) determine which of such agents  
2 present a material threat against the  
3 United States population.

4 “(B) PUBLIC HEALTH IMPACT; NECESSARY  
5 COUNTERMEASURES.—The Secretary shall on  
6 an ongoing basis—

7 “(i) assess the potential public health  
8 consequences of use against the United  
9 States population of agents identified  
10 under subparagraph (A)(ii); and

11 “(ii) determine, on the basis of such  
12 assessment, the agents for which priority  
13 countermeasures are necessary to protect  
14 the public health from a material threat.

15 “(C) NOTICE TO CONGRESS.—The Sec-  
16 retary and the Homeland Security Secretary  
17 shall promptly notify the designated congres-  
18 sional committees (as defined in paragraph (10)  
19 that a determination has been made pursuant  
20 to subparagraph (A) or (B). Such notice shall  
21 be in unclassified or, if necessary, classified  
22 form.

23 “(D) ASSURING ACCESS TO THREAT IN-  
24 FORMATION.—In making the assessment and  
25 determination required under subparagraph

1 (A), the Homeland Security Secretary shall use  
2 all information to which such Secretary is enti-  
3 tled under section 202 of the Homeland Secu-  
4 rity Act of 2002, including but not limited to  
5 information, regardless of its level of classifica-  
6 tion, relating to current and emerging threats  
7 of chemical, biological, radiological, and nuclear  
8 agents.

9 “(3) ASSESSMENT OF AVAILABILITY AND AP-  
10 PROPRIATENESS OF COUNTERMEASURES.—The Sec-  
11 retary, in consultation with the Homeland Security  
12 Secretary, shall assess on an ongoing basis the avail-  
13 ability and appropriateness of specific counter-  
14 measures to address specific threats identified under  
15 paragraph (2).

16 “(4) CALL FOR DEVELOPMENT OF COUNTER-  
17 MEASURES; COMMITMENT FOR RECOMMENDATION  
18 FOR PROCUREMENT.—

19 “(A) PROPOSAL TO THE PRESIDENT.—If,  
20 pursuant to an assessment under paragraph  
21 (3), the Homeland Security Secretary and the  
22 Secretary make a determination that a counter-  
23 measure would be appropriate but is either cur-  
24 rently unavailable for procurement as a security  
25 countermeasure or is approved, licensed, or

1 cleared only for alternative uses, such Secre-  
2 taries may jointly submit to the President a  
3 proposal to—

4 “(i) issue a call for the development of  
5 such countermeasure; and

6 “(ii) make a commitment that, upon  
7 the first development of such counter-  
8 measure that meets the conditions for pro-  
9 curement under paragraph (5), the Secre-  
10 taries will, based in part on information  
11 obtained pursuant to such call, make a rec-  
12 ommendation under paragraph (6) that the  
13 special reserve fund under paragraph (10)  
14 be made available for the procurement of  
15 such countermeasure.

16 “(B) COUNTERMEASURE SPECIFICA-  
17 TIONS.—The Homeland Security Secretary and  
18 the Secretary shall, to the extent practicable,  
19 include in the proposal under subparagraph  
20 (A)—

21 “(i) estimated quantity of purchase  
22 (in the form of number of doses or number  
23 of effective courses of treatments regard-  
24 less of dosage form);

1 “(ii) necessary measures of minimum  
2 safety and effectiveness;

3 “(iii) estimated price for each dose or  
4 effective course of treatment regardless of  
5 dosage form; and

6 “(iv) other information that may be  
7 necessary to encourage and facilitate re-  
8 search, development, and manufacture of  
9 the countermeasure or to provide specifica-  
10 tions for the countermeasure.

11 “(C) PRESIDENTIAL APPROVAL.—If the  
12 President approves a proposal under subpara-  
13 graph (A), the Homeland Security Secretary  
14 and the Secretary shall make known to persons  
15 who may respond to a call for the counter-  
16 measure involved—

17 “(i) the call for the countermeasure;

18 “(ii) specifications for the counter-  
19 measure under subparagraph (B); and

20 “(iii) the commitment described in  
21 subparagraph (A)(ii).

22 “(5) SECRETARY’S DETERMINATION OF COUN-  
23 TERMEASURES APPROPRIATE FOR FUNDING FROM  
24 SPECIAL RESERVE FUND.—

1           “(A) IN GENERAL.—The Secretary, in ac-  
2           cordance with the provisions of this paragraph,  
3           shall identify specific security countermeasures  
4           that the Secretary determines, in consultation  
5           with the Homeland Security Secretary, to be  
6           appropriate for inclusion in the stockpile under  
7           subsection (a) pursuant to procurements made  
8           with amounts in the special reserve fund under  
9           paragraph (10) (referred to in this subsection  
10          individually as a ‘procurement under this sub-  
11          section’).

12          “(B) REQUIREMENTS.—In making a deter-  
13          mination under subparagraph (A) with respect  
14          to a security countermeasure, the Secretary  
15          shall determine and consider the following:

16               “(i) The quantities of the product  
17               that will be needed to meet the needs of  
18               the stockpile.

19               “(ii) The feasibility of production and  
20               delivery within five years of sufficient  
21               quantities of the product.

22               “(iii) Whether there is a lack of a sig-  
23               nificant commercial market for the product  
24               at the time of procurement, other than as  
25               a security countermeasure.

1           “(6) RECOMMENDATION FOR PRESIDENT’S AP-  
2       PROVAL.—

3           “(A) RECOMMENDATION FOR PROCURE-  
4       MENT.—In the case of a security counter-  
5       measure that the Secretary has, in accordance  
6       with paragraphs (3) and (5), determined to be  
7       appropriate for procurement under this sub-  
8       section, the Homeland Security Secretary and  
9       the Secretary shall jointly submit to the Presi-  
10      dent, in coordination with the Director of the  
11      Office of Management and Budget, a rec-  
12      ommendation that the special reserve fund  
13      under paragraph (10) be made available for the  
14      procurement of such countermeasure.

15           “(B) PRESIDENTIAL APPROVAL.—The spe-  
16      cial reserve fund under paragraph (10) is avail-  
17      able for a procurement of a security counter-  
18      measure only if the President has approved a  
19      recommendation under subparagraph (A) re-  
20      garding the countermeasure.

21           “(C) NOTICE TO DESIGNATED CONGRES-  
22      SIONAL COMMITTEES.—The Secretary and the  
23      Homeland Security Secretary shall notify the  
24      designated congressional committees of each de-  
25      cision of the President to approve a rec-

ommendation under subparagraph (A). Such notice shall include an explanation of the decision to make available the special reserve fund under paragraph (10) for procurement of such a countermeasure, including, where available, the identification of the potential supplier or suppliers of such countermeasure, and whether other potential suppliers of the same or similar countermeasures were considered and rejected for procurement under this section and the reasons therefor.

“(D) SUBSEQUENT SPECIFIC COUNTERMEASURES.—Procurement under this subsection of a security countermeasure for a particular purpose does not preclude the subsequent procurement under this subsection of any other security countermeasure for such purpose if the Secretary has determined under paragraph (5)(A) that such countermeasure is appropriate for inclusion in the stockpile and if, as determined by the Secretary, such countermeasure provides improved safety or effectiveness, or for other reasons enhances preparedness to respond to threats of use of a biological, chemical, radiological, or nuclear agent. Such a

determination by the Secretary is committed to agency discretion.

“(E) RULE OF CONSTRUCTION.—Recommendations and approvals under this paragraph apply solely to determinations that the special reserve fund under paragraph (10) will be made available for a procurement of a security countermeasure, and not to the substance of contracts for such procurement or other matters relating to awards of such contracts.

“(7) PROCUREMENT.—

“(A) IN GENERAL.—For purposes of a procurement under this subsection that is approved by the President under paragraph (6), the Homeland Security Secretary and the Secretary shall have responsibilities in accordance with subparagraphs (B) and (C).

“(B) INTERAGENCY AGREEMENTS.—

“(i) FOR PROCUREMENT.—The Homeland Security Secretary shall enter into an agreement with the Secretary for procurement of a security countermeasure in accordance with the provisions of this paragraph. The special reserve fund under paragraph (10) shall be available for the



Secretary's costs of such procurement,  
other than as provided in clause (ii).

“(ii) FOR ADMINISTRATIVE COSTS.—

The agreement entered into between the  
Homeland Security Secretary and the Sec-  
retary for managing the stockpile under  
subsection (a) shall provide for reimburse-  
ment of the Secretary's administrative  
costs relating to procurements under this  
subsection.

“(C) PROCUREMENT.—

“(i) IN GENERAL.—The Secretary  
shall be responsible for—

“(I) arranging for procurement  
of a security countermeasure, includ-  
ing negotiating terms (including quan-  
tity, production schedule, and price)  
of, and entering into, contracts and  
cooperative agreements, and for car-  
rying out such other activities as may  
reasonably be required, in accordance  
with the provisions of this subpara-  
graph; and

“(II) promulgating such regula-  
tions as the Secretary determines nec-

1           essary to implement the provisions of  
2           this subsection.

3           “(ii) CONTRACT TERMS.—A contract  
4           for procurements under this subsection  
5           shall (or, as specified below, may) include  
6           the following terms:

7                         “(I) PAYMENT CONDITIONED ON  
8                         SUBSTANTIAL DELIVERY.—The con-  
9                         tract shall provide that no payment  
10                        may be made until delivery has been  
11                        made of a substantial portion (as de-  
12                        termined by the Secretary) of the  
13                        total number of units contracted for,  
14                        except that, notwithstanding any  
15                        other provision of law, the contract  
16                        may provide that, if the Secretary de-  
17                        termines (in the Secretary’s discre-  
18                        tion) that an advance payment is nec-  
19                        essary to ensure success of a project,  
20                        the Secretary may pay an amount, not  
21                        to exceed 10 percent of the contract  
22                        amount, in advance of delivery. The  
23                        contract shall provide that such ad-  
24                        vance payment is required to be re-  
25                        paid if there is a failure to perform

1 under the contract, except in special  
2 circumstances as determined by the  
3 Secretary on a contract by contract  
4 basis. Nothing in this subclause may  
5 be construed as affecting rights of  
6 vendors under provisions of law or  
7 regulation (including the Federal Ac-  
8 quisition Regulation) relating to ter-  
9 mination of contracts for the conven-  
10 ience of the Government.

11 “(II) CONTRACT DURATION.—  
12 The contract shall be for a period not  
13 to exceed five years, except that, in  
14 first awarding the contract, the Sec-  
15 retary may provide for a longer dura-  
16 tion, not exceeding eight years, if the  
17 Secretary determines that complexities  
18 or other difficulties in performance  
19 under the contract justify such a pe-  
20 riod. The contract shall be renewable  
21 for additional periods, none of which  
22 shall exceed five years.

23 “(III) STORAGE BY VENDOR.—  
24 The contract may provide that the  
25 vendor will provide storage for stocks

1 of a product delivered to the owner-  
2 ship of the Federal Government under  
3 the contract, for such period and  
4 under such terms and conditions as  
5 the Secretary may specify, and in  
6 such case amounts from the special  
7 reserve fund under paragraph (10)  
8 shall be available for costs of ship-  
9 ping, handling, storage, and related  
10 costs for such product.

11 “(IV) NON-STOCKPILE TRANS-  
12 FERS OF SECURITY COUNTER-  
13 MEASURES.—The contract shall pro-  
14 vide that the vendor will comply with  
15 all applicable export-related controls  
16 with respect to such countermeasure.

17 “(iii) AVAILABILITY OF SIMPLIFIED  
18 ACQUISITION PROCEDURES.—

19 “(I) IN GENERAL.—If the Sec-  
20 retary determines that there is a  
21 pressing need for a procurement of a  
22 specific countermeasure, the amount  
23 of the procurement under this sub-  
24 section shall be deemed to be below  
25 the threshold amount specified in sec-

tion 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11)), for purposes of application to such procurement, pursuant to section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a)), of—

“(aa) section 303(g)(1)(A) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(g)(1)(A)) and its implementing regulations; and

“(bb) section 302A(b) of such Act (41 U.S.C. 252a(b)) and its implementing regulations.

“(II) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding subclause (I) and the provision of law and regulations referred to in such clause, each of the following provisions shall apply to procurements described in this clause to the same extent that such provisions would apply to such procurements in the absence of subclause (I):

1 “(aa) Chapter 37 of title 40,  
2 United States Code (relating to  
3 contract work hours and safety  
4 standards).

5 “(bb) Subsections (a) and  
6 (b) of section 7 of the Anti-Kick-  
7 back Act of 1986 (41 U.S.C.  
8 57(a) and (b)).

9 “(cc) Section 304C of the  
10 Federal Property and Adminis-  
11 trative Services Act of 1949 (41  
12 U.S.C. 254d) (relating to the ex-  
13 amination of contractor records).

14 “(iv) PROCEDURES OTHER THAN  
15 FULL AND OPEN COMPETITION.—

16 “(I) IN GENERAL.—In using the  
17 authority provided in section  
18 303(c)(1) of title III of the Federal  
19 Property and Administrative Services  
20 Act of 1949 (41 U.S.C. 253(c)(1)) to  
21 use procedures other than competitive  
22 procedures in the case of a procure-  
23 ment under this subsection, the  
24 phrase ‘available from only one re-  
25 sponsible source’ in such section

1 303(c)(1) shall be deemed to mean  
2 ‘available from only one responsible  
3 source or only from a limited number  
4 of responsible sources’.

5 “(II) RELATION TO OTHER AU-  
6 THORITIES.—The authority under  
7 subclause (I) is in addition to any  
8 other authority to use procedures  
9 other than competitive procedures.

10 “(III) APPLICABLE GOVERN-  
11 MENT-WIDE REGULATIONS.—The Sec-  
12 retary shall implement this clause in  
13 accordance with applicable govern-  
14 ment-wide regulations, including re-  
15 quirements that offers be solicited  
16 from as many potential sources as is  
17 practicable under the circumstances,  
18 that required notices be published,  
19 and that submitted offers be consid-  
20 ered.

21 “(v) PREMIUM PROVISION IN MUL-  
22 TIPLE AWARD CONTRACTS.—

23 “(I) IN GENERAL.—If, under this  
24 subsection, the Secretary enters into  
25 contracts with more than one vendor

1 to procure a security countermeasure,  
2 such Secretary may, notwithstanding  
3 any other provision of law, include in  
4 each of such contracts a provision  
5 that—

6 “(aa) identifies an increment  
7 of the total quantity of security  
8 countermeasure required, wheth-  
9 er by percentage or by numbers  
10 of units; and

11 “(bb) promises to pay one or  
12 more specified premiums based  
13 on the priority of such vendors’  
14 production and delivery of the in-  
15 crement identified under item  
16 (aa), in accordance with the  
17 terms and conditions of the con-  
18 tract.

19 “(II) DETERMINATION OF GOV-  
20 ERNMENT’S REQUIREMENT NOT RE-  
21 VIEWABLE.—If the Secretary includes  
22 in each of a set of contracts a provi-  
23 sion as described in subclause (I),  
24 such Secretary’s determination of the  
25 total quantity of security counter-



1 measure required, and any amend-  
2 ment of such determination, is com-  
3 mitted to agency discretion.

4 “(vi) EXTENSION OF CLOSING DATE  
5 FOR RECEIPT OF PROPOSALS NOT REVIEW-  
6 ABLE.—A decision by the Secretary to ex-  
7 tend the closing date for receipt of pro-  
8 posals for a procurement under this sub-  
9 section is committed to agency discretion.

10 “(vii) LIMITING COMPETITION TO  
11 SOURCES RESPONDING TO REQUEST FOR  
12 INFORMATION.—In conducting a procure-  
13 ment under this subsection, the Secretary  
14 may exclude a source that has not re-  
15 sponded to a request for information under  
16 section 303A(a)(1)(B) of the Federal  
17 Property and Administrative Services Act  
18 of 1949 (41 U.S.C. 253a(a)(1)(B)) if such  
19 request has given notice that the Secretary  
20 may so exclude such a source.

21 “(8) INTERAGENCY COOPERATION.—

22 “(A) IN GENERAL.—In carrying out activi-  
23 ties under this section, the Homeland Security  
24 Secretary and the Secretary are authorized,  
25 subject to subparagraph (B), to enter into

1 interagency agreements and other collaborative  
2 undertakings with other agencies of the United  
3 States Government.

4 “(B) LIMITATION.—An agreement or un-  
5 dertaking under this paragraph shall not au-  
6 thorize another agency to exercise the authori-  
7 ties provided by this section to the Homeland  
8 Security Secretary or to the Secretary.

9 “(9) RESTRICTIONS ON USE OF FUNDS.—  
10 Amounts in the special reserve fund under para-  
11 graph (10) shall not be used to pay—

12 “(A) costs for the purchase of vaccines  
13 under procurement contracts entered into be-  
14 fore the date of the enactment of the Project  
15 BioShield Act of 2003; or

16 “(B) administrative costs.

17 “(10) DEFINITIONS.—

18 “(A) SPECIAL RESERVE FUND.—For pur-  
19 poses of this subsection, the term ‘special re-  
20 serve fund’ has the meaning given such term in  
21 section 510 of the Homeland Security Act of  
22 2002.

23 “(B) DESIGNATED CONGRESSIONAL COM-  
24 MITTEES.—For purposes of this section, the  
25 term ‘designated congressional committees’

1 means the following committees of the Con-  
2 gress:

3 “(i) In the House of Representatives:  
4 the Committee on Energy and Commerce,  
5 the Committee on Appropriations, the  
6 Committee on Government Reform, and  
7 the Select Committee on Homeland Secu-  
8 rity (or any successor to the Select Com-  
9 mittee).

10 “(ii) In the Senate: the Committee on  
11 Health, Education, Labor, and Pensions,  
12 the Committee on Appropriations, and the  
13 Committee on Government Affairs.

14 “(d) DISCLOSURES.—No Federal agency shall dis-  
15 close under section 552 of title 5, United States Code, any  
16 information identifying the location at which materials in  
17 the stockpile under subsection (a) are stored.

18 “(e) DEFINITION.—For purposes of subsection (a),  
19 the term ‘stockpile’ includes—

20 “(1) a physical accumulation (at one or more  
21 locations) of the supplies described in subsection (a);  
22 or

23 “(2) a contractual agreement between the Sec-  
24 retary and a vendor or vendors under which such

1 vendor or vendors agree to provide to such Secretary  
 2 supplies described in subsection (a).

3 “(f) AUTHORIZATION OF APPROPRIATIONS.—

4 “(1) STRATEGIC NATIONAL STOCKPILE.—For  
 5 the purpose of carrying out subsection (a), there are  
 6 authorized to be appropriated \$640,000,000 for fis-  
 7 cal year 2002, and such sums as may be necessary  
 8 for each of fiscal years 2003 through 2006. Such  
 9 authorization is in addition to amounts in the special  
 10 reserve fund under subsection (c)(10).

11 “(2) SMALLPOX VACCINE DEVELOPMENT.—For  
 12 the purpose of carrying out subsection (b), there are  
 13 authorized to be appropriated \$509,000,000 for fis-  
 14 cal year 2002, and such sums as may be necessary  
 15 for each of fiscal years 2003 through 2006.”.

16 (b) AMENDMENT TO HOMELAND SECURITY ACT OF  
 17 2002.—Title V of the Homeland Security Act of 2002  
 18 (116 Stat. 2212; 6 U.S.C. 311 et seq.) is amended by add-  
 19 ing at the end the following:

20 **“SEC. 510. PROCUREMENT OF SECURITY COUNTER-**  
 21 **MEASURES FOR STRATEGIC NATIONAL**  
 22 **STOCKPILE.**

23 “(a) AUTHORIZATION OF APPROPRIATIONS.—For the  
 24 procurement of security countermeasures under section  
 25 319F–2(c) of the Public Health Service Act (referred to

1 in this section as the ‘security countermeasures program’),  
2 there is authorized to be appropriated up to  
3 \$5,593,000,000 for the fiscal years 2004 through 2013.  
4 Of the amounts appropriated under the preceding sen-  
5 tence, not to exceed \$3,418,000,000 may be obligated dur-  
6 ing the fiscal years 2004 through 2008, of which not to  
7 exceed \$890,000,000 may be obligated during fiscal year  
8 2004.

9 “(b) SPECIAL RESERVE FUND.—For purposes of the  
10 security countermeasures program, the term ‘special re-  
11 serve fund’ means the appropriations account established  
12 as a result of any appropriations made under subsection  
13 (a).

14 “(c) AVAILABILITY.—

15 “(1) INTEGRITY OF SPECIAL RESERVE FUND;  
16 LIMITATION OF OBLIGATIONAL AUTHORITY TO FUND  
17 PURPOSES; INTENT OF CONGRESS AGAINST RE-  
18 PROGRAMMING.—Subject to paragraph (2), all  
19 amounts appropriated under subsection (a) are  
20 available for obligation through the end of fiscal year  
21 2013 and only for the specific purposes set forth in  
22 the security countermeasures program. It is the in-  
23 tent of the Congress that no portion of such amount  
24 that remains unobligated for such purposes shall be

1 applied, through reprogramming or otherwise, to any  
2 other purpose.

3 “(2) INITIAL AVAILABILITY FOR PARTICULAR  
4 PROCUREMENTS.—Amounts appropriated under sub-  
5 section (a) become available for a procurement  
6 under the security countermeasures program only  
7 upon the approval by the President of such avail-  
8 ability for the procurement in accordance with para-  
9 graph (6)(B) of such program.

10 “(d) RELATED AUTHORIZATIONS OF APPROPRIA-  
11 TIONS.—

12 “(1) THREAT ASSESSMENT CAPABILITIES.—For  
13 the purpose of carrying out the responsibilities of  
14 the Secretary for terror threat assessment under the  
15 security countermeasures program, there are author-  
16 ized to be appropriated \$5,000,000 for fiscal year  
17 2003, and such sums as may be necessary for each  
18 of the fiscal years 2004 through 2006, for the hiring  
19 of professional personnel within the Directorate for  
20 Information Analysis and Infrastructure Protection,  
21 who shall be analysts responsible for chemical, bio-  
22 logical, radiological, and nuclear threat assessment  
23 (including but not limited to analysis of chemical, bi-  
24 ological, radiological, and nuclear agents, the means  
25 by which such agents could be weaponized or used

1 in a terrorist attack, and the capabilities, plans, and  
2 intentions of terrorists and other non-state actors  
3 who may have or acquire such agents). All such ana-  
4 lysts shall meet the applicable standards and quali-  
5 fications for the performance of intelligence activities  
6 promulgated by the Director of Central Intelligence  
7 pursuant to section 104 of the National Security Act  
8 of 1947.

9 “(2) INTELLIGENCE SHARING INFRASTRUC-  
10 TURE.—For the purpose of carrying out the acquisi-  
11 tion and deployment of secure facilities (including  
12 information technology and physical infrastructure,  
13 whether mobile and temporary, or permanent) suffi-  
14 cient to permit the Secretary to receive, not later  
15 than December 31, 2003, all classified information  
16 and products to which the Under Secretary for In-  
17 formation Analysis and Infrastructure Protection is  
18 entitled under subtitle A of title II, there are author-  
19 ized to be appropriated such sums as may be nec-  
20 essary for each of the fiscal years 2003 through  
21 2006.”.

1 **SEC. 4. AUTHORIZATION FOR MEDICAL PRODUCTS FOR**  
2 **USE IN EMERGENCIES.**

3 Subchapter E of chapter V of the Federal Food,  
4 Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is  
5 amended by adding at the end the following section:

6 **“SEC. 564. AUTHORIZATION FOR MEDICAL PRODUCTS FOR**  
7 **USE IN EMERGENCIES.**

8 “(a) IN GENERAL.—

9 “(1) EMERGENCY USES.—Notwithstanding sec-  
10 tions 505, 510(k), and 515 of this Act and section  
11 351 of the Public Health Service Act, and subject to  
12 the provisions of this section, the Secretary may au-  
13 thorize the introduction into interstate commerce,  
14 during the effective period of a declaration under  
15 subsection (b), of a drug, device, or biological prod-  
16 uct intended for use in an actual or potential emer-  
17 gency (referred to in this section as an ‘emergency  
18 use’).

19 “(2) APPROVAL STATUS OF PRODUCT.—An au-  
20 thorization under paragraph (1) may authorize an  
21 emergency use of a product that—

22 “(A) is not approved, licensed, or cleared  
23 for commercial distribution under a provision of  
24 law referred to in such paragraph (referred to  
25 in this section as an ‘unapproved product’); or



1           “(B) is approved, licensed, or cleared  
2           under such a provision, but which use is not  
3           under such provision an approved, licensed, or  
4           cleared use of the product (referred to in this  
5           section as an ‘unapproved use of an approved  
6           product’).

7           “(3) RELATION TO OTHER USES.—An emer-  
8           gency use authorized under paragraph (1) for a  
9           product is in addition to any other use that is au-  
10          thorized for the product under a provision of law re-  
11          ferred to in such paragraph.

12          “(4) DEFINITIONS.—For purposes of this sec-  
13          tion:

14               “(A) The term ‘biological product’ has the  
15               meaning given such term in section 351 of the  
16               Public Health Service Act.

17               “(B) The term ‘emergency use’ has the  
18               meaning indicated for such term in paragraph  
19               (1).

20               “(C) The term ‘product’ means a drug, de-  
21               vice, or biological product.

22               “(D) The term ‘unapproved product’ has  
23               the meaning indicated for such term in para-  
24               graph (2)(A).

1           “(E) The term ‘unapproved use of an ap-  
2           proved product’ has the meaning indicated for  
3           such term in paragraph (2)(B).

4           “(b) DECLARATION OF EMERGENCY.—

5           “(1) IN GENERAL.—The Secretary may declare  
6           an emergency justifying the authorization under this  
7           subsection for a product on the basis of—

8           “(A) a determination by the Secretary of  
9           Homeland Security that there is a national  
10          emergency, or a significant potential for a na-  
11          tional emergency, involving a heightened risk of  
12          attack with a specified biological, chemical, ra-  
13          diological, or nuclear agent or agents;

14          “(B) a determination by the Secretary of  
15          Defense that there is a military emergency, or  
16          a significant potential for a military emergency,  
17          involving a heightened risk to United States  
18          military forces of attack with a biological,  
19          chemical, radiological, or nuclear agent or  
20          agents; or

21          “(C) a determination by the Secretary of a  
22          public health emergency under section 319 of  
23          the Public Health Service Act, affecting na-  
24          tional security and involving a specified biologi-  
25          cal, chemical, radiological, or nuclear agent or

1 agents, or a specified disease or condition that  
2 may be attributable to such agent or agents.

3 “(2) TERMINATION OF DECLARATION.—

4 “(A) IN GENERAL.—A declaration under  
5 this subsection shall terminate upon the earlier  
6 of—

7 “(i) a determination by the Secretary,  
8 in consultation as appropriate with the  
9 Secretary of Homeland Security or the  
10 Secretary of Defense, that the cir-  
11 cumstances described in paragraph (1)  
12 have ceased to exist; or

13 “(ii) the expiration of the one-year pe-  
14 riod beginning on the date on which the  
15 declaration is made.

16 “(B) RENEWAL.—Notwithstanding sub-  
17 paragraph (A), the Secretary may renew a dec-  
18 laration under this subsection, and this para-  
19 graph shall apply to any such renewal.

20 “(3) ADVANCE NOTICE OF TERMINATION.—In  
21 terminating a declaration under this section, the  
22 Secretary shall provide advance notice that the dec-  
23 laration will be terminated. The period of advance  
24 notice shall be a period reasonably determined to  
25 provide—

1           “(A) in the case of an unapproved product,  
2           a sufficient period for disposition of shipments  
3           of the product, including the return of such  
4           shipments to the manufacturer (in the case of  
5           a manufacturer that chooses to have the ship-  
6           ments returned); and

7           “(B) in the case of unapproved uses of ap-  
8           proved products, a sufficient period for the dis-  
9           position of any labeling that was provided with  
10          respect to the emergency use involved.

11          “(4) PUBLICATION.—The Secretary shall  
12          promptly publish in the Federal Register each dec-  
13          laration, determination, and renewal under this sub-  
14          section.

15          “(c) CRITERIA FOR ISSUANCE OF AUTHORIZATION.—  
16          The Secretary may issue an authorization under this sec-  
17          tion with respect to the emergency use of a product only  
18          if, after consultation with the Director of the National In-  
19          stitutes of Health and the Director of the Centers for Dis-  
20          ease Control and Prevention, to the extent feasible and  
21          appropriate given the circumstances of the emergency in-  
22          volved, the Secretary concludes—

23               “(1) that an agent specified in a declaration  
24               under subsection (b) can cause a serious or life-  
25               threatening disease or condition;

1           “(2) that, based on the totality of scientific evi-  
2           dence available to the Secretary, including data from  
3           adequate and well-controlled clinical trials, if avail-  
4           able, it is reasonable to believe that—

5                   “(A) the product may be effective in de-  
6                   tecting, diagnosing, treating, or preventing—

7                           “(i) such disease or condition; or

8                           “(ii) a serious or life-threatening dis-  
9                           ease or condition caused by a product au-  
10                          thorized under this section or approved  
11                          under this Act or the Public Health Serv-  
12                          ice Act, for detecting, diagnosing, treating,  
13                          or preventing such a disease or condition  
14                          caused by such an agent; and

15                   “(B) the known and potential benefits of  
16                   the product, when used to detect, diagnose, pre-  
17                   vent, or treat such disease or condition, out-  
18                   weigh the known and potential risks of the  
19                   product;

20           “(3) that there is no adequate, approved, and  
21           available alternative to the product for detecting, di-  
22           agnosing, preventing, or treating such disease or  
23           condition; and

24           “(4) that such other criteria as the Secretary  
25           may by regulation prescribe are satisfied.

1 “(d) SCOPE OF AUTHORIZATION.—

2 “(1) IN GENERAL.—An authorization of a prod-  
3 uct under this section shall state—

4 “(A) each disease or condition that the  
5 product may be used to detect, diagnose, pre-  
6 vent, or treat within the scope of the authoriza-  
7 tion;

8 “(B) the Secretary’s conclusions, made  
9 under subsection (c)(2)(B), that the known and  
10 potential benefits of the product, when used to  
11 detect, diagnose, prevent, or treat such disease  
12 or condition, outweigh the known and potential  
13 risks of the product; and

14 “(C) the Secretary’s conclusions, made  
15 under subsection (c), concerning the safety and  
16 potential effectiveness of the product in detect-  
17 ing, diagnosing, preventing, or treating such  
18 diseases or conditions, including an assessment  
19 of the available scientific evidence.

20 “(2) CONFIDENTIAL INFORMATION.—Nothing  
21 in this section alters or amends section 1905 of title  
22 18, United States Code, or section 552(b)(4) of title  
23 5 of such Code.

24 “(e) CONDITIONS OF AUTHORIZATION.—

25 “(1) UNAPPROVED PRODUCT.—

1           “(A) REQUIRED CONDITIONS.—With re-  
2           spect to the emergency use of an unapproved  
3           product, the Secretary, to the extent feasible  
4           given the circumstances of the emergency, shall,  
5           for persons who choose to carry out one or  
6           more activities for which the authorization is  
7           issued, establish such conditions on an author-  
8           ization under this section as the Secretary finds  
9           necessary or appropriate to protect the public  
10          health, including the following:

11                 “(i) Appropriate conditions designed  
12                 to ensure that, to the extent feasible given  
13                 the circumstances of the emergency, health  
14                 care professionals administering the prod-  
15                 uct are informed—

16                         “(I) that the Secretary has au-  
17                         thorized the emergency use of the  
18                         product;

19                         “(II) of the significant known  
20                         and potential benefits and risks of the  
21                         emergency use of the product, and of  
22                         the extent to which such benefits and  
23                         risks are unknown; and

1 “(III) of the alternatives to the  
2 product that are available, and of  
3 their benefits and risks.

4 “(ii) Appropriate conditions designed  
5 to ensure that, to the extent feasible given  
6 the circumstances of the emergency, indi-  
7 viduals to whom the product is adminis-  
8 tered are informed—

9 “(I) that the Secretary has au-  
10 thorized the emergency use of the  
11 product;

12 “(II) of the significant known  
13 and potential benefits and risks of  
14 such use, and of the extent to which  
15 such benefits and risks are unknown;  
16 and

17 “(III) of the option to accept or  
18 refuse administration of the product,  
19 of the consequences, if any, of refus-  
20 ing administration of the product, and  
21 of the alternatives to the product that  
22 are available and of their benefits and  
23 risks.

24 “(iii) Appropriate conditions for the  
25 monitoring and reporting of adverse events



1 associated with the emergency use of the  
2 product.

3 “(iv) For manufacturers of the prod-  
4 uct, appropriate conditions concerning rec-  
5 ordkeeping and reporting, including  
6 records access by the Secretary, with re-  
7 spect to the emergency use of the product.

8 “(B) AUTHORITY FOR ADDITIONAL CONDI-  
9 TIONS.—With respect to the emergency use of  
10 an unapproved product, the Secretary, to the  
11 extent feasible given the circumstances of the  
12 emergency, may, for persons who choose to  
13 carry out one or more activities for which the  
14 authorization is issued, establish such condi-  
15 tions on an authorization under this section as  
16 the Secretary finds necessary or appropriate to  
17 protect the public health, including the fol-  
18 lowing:

19 “(i) Appropriate conditions on which  
20 entities may distribute the product with re-  
21 spect to the emergency use of the product  
22 (including limitation to distribution by gov-  
23 ernment entities), and on how distribution  
24 is to be performed.

1           “(ii) Appropriate conditions on who  
2           may administer the product with respect to  
3           the emergency use of the product, and on  
4           the categories of individuals to whom, and  
5           the circumstances under which, the prod-  
6           uct may be administered with respect to  
7           such use.

8           “(iii) For persons other than manu-  
9           facturers of the product, appropriate con-  
10          ditions concerning recordkeeping and re-  
11          porting, including records access by the  
12          Secretary, with respect to the emergency  
13          use of the product.

14          “(iv) With respect to the emergency  
15          use of the product, waive or limit, to the  
16          extent appropriate given the circumstances  
17          of the emergency, conditions regarding  
18          current good manufacturing practice other-  
19          wise applicable to the manufacture, proc-  
20          essing, packing, or holding of products  
21          subject to regulation under this Act, in-  
22          cluding such requirements established in  
23          section 501.

1           “(2) UNAPPROVED USE.—With respect to the  
2           emergency use of a product that is an unapproved  
3           use of an approved product:

4                   “(A) The Secretary may, for manufactur-  
5                   ers of the product who choose to carry out one  
6                   or more activities for which the authorization is  
7                   issued, establish any of the conditions described  
8                   in clauses (i) through (iv) of paragraph (1)(A).

9                   “(B)(i) If the authorization under this sec-  
10                  tion regarding the emergency use authorizes a  
11                  change in the labeling of the product, but the  
12                  manufacturer of the product chooses not to  
13                  make such change, such authorization may not  
14                  authorize distributors of the product or any  
15                  other person to alter or obscure the labeling  
16                  provided by the manufacturer.

17                  “(ii) In the circumstances described in  
18                  clause (i), an authorization under this section  
19                  regarding the emergency use may, for persons  
20                  who do not manufacture the product and who  
21                  choose to act under this clause, authorize such  
22                  persons to provide information on the product  
23                  in addition to the labeling provided by the man-  
24                  ufacturer, subject to compliance with clause (i).

1           Such additional information shall not be consid-  
2           ered labeling for purposes of section 502.

3           “(f) DURATION OF AUTHORIZATION.—

4           “(1) IN GENERAL.—Except as provided in para-  
5           graph (2), an authorization under this section shall  
6           be effective until the earlier of the termination of the  
7           declaration under subsection (b) or a revocation  
8           under subsection (g).

9           “(2) CONTINUED USE AFTER END OF EFFEC-  
10          TIVE PERIOD.—Notwithstanding the termination of  
11          the declaration under subsection (b) or a revocation  
12          under subsection (g), an authorization shall continue  
13          to be effective for continued use with respect to pa-  
14          tients to whom it was administered during the pe-  
15          riod described by paragraph (1), to the extent found  
16          necessary by such patients’ attending physicians.

17          “(g) REVOCATION OF AUTHORIZATION.—

18          “(1) REVIEW.—The Secretary shall periodically  
19          review the circumstances and the appropriateness of  
20          an authorization under this section.

21          “(2) REVOCATION.—The Secretary may revoke  
22          an authorization under this section if, in the Sec-  
23          retary’s unreviewable discretion, the criteria under  
24          subsection (c) for issuance of such authorization are  
25          no longer met.

1       “(h) PUBLICATION.—The Secretary shall promptly  
2 publish in the Federal Register a notice of each authoriza-  
3 tion, and each termination or revocation of an authoriza-  
4 tion, and an explanation of the reasons therefor, under  
5 this section.

6       “(i) ACTIONS COMMITTED TO AGENCY DISCRE-  
7 TION.—Actions under the authority of this section by the  
8 Secretary, by the Secretary of Defense, or by the Sec-  
9 retary of Homeland Security are committed to agency dis-  
10 cretion.

11       “(j) RULES OF CONSTRUCTION.—Nothing in this sec-  
12 tion shall be construed to impair or otherwise affect—

13               “(1) the authority of the President as Com-  
14 mander in Chief of the Armed Forces of the United  
15 States under article II, section 2 of the United  
16 States Constitution;

17               “(2) the authority of the Secretary of Defense  
18 with respect to the Department of Defense, includ-  
19 ing the armed forces, under other provisions of Fed-  
20 eral law; or

21               “(3) the authority of the Secretary under sec-  
22 tion 319F–2 to manage the stockpile under such  
23 section.

24       “(k) APPLICATION TO MEMBERS OF ARMED  
25 FORCES.—

1           “(1) WAIVER OF REQUIREMENT RELATING TO  
2           OPTION TO REFUSE.—In the case of administration  
3           of a countermeasure to members of the armed  
4           forces, a requirement, under subsection  
5           (e)(1)(A)(ii)(III), designed to ensure that individuals  
6           are informed of an option to accept or refuse admin-  
7           istration of a product, may be waived by the Presi-  
8           dent if the President determines, in writing, that  
9           complying with such requirement is not feasible, is  
10          contrary to the best interests of the members af-  
11          fected, or is not in the interests of national security.

12          “(2) PROVISION OF INFORMATION TO MEMBER  
13          OF THE ARMED FORCES.—If the Secretary makes a  
14          determination that it is not feasible for the informa-  
15          tion required by subsection (e)(1)(A)(ii) to be pro-  
16          vided to a member of the armed forces prior to the  
17          administration of the product, such information shall  
18          be provided to such member of the armed forces (or  
19          next-of-kin in the case of the death of a member) to  
20          whom the product was administered as soon as pos-  
21          sible, but not later than 30 days, after such adminis-  
22          tration. Information concerning the administration  
23          of the product shall be recorded in the medical  
24          record of the member.

1           “(3) EFFECT ON STATUTE PERTAINING TO IN-  
2           VESTIGATIONAL NEW DRUGS.—In the case of an au-  
3           thorization based on a determination by the Sec-  
4           retary of Defense under subsection (b)(1)(B), sec-  
5           tion 1107 of title 10, United States Code, shall not  
6           apply to use of a product that is the subject of such  
7           authorization, within the scope of such authorization  
8           and while such authorization is effective.

9           “(l) RELATION TO OTHER PROVISIONS.—If a prod-  
10          uct is the subject of an authorization under this section,  
11          the use of such product within the scope of the authoriza-  
12          tion —

13               “(1) shall not be subject to any requirements  
14               pursuant to section 505(i) or 520(g); and

15               “(2) shall not be subject to any requirements  
16               otherwise applicable to clinical investigations pursu-  
17               ant to other provisions of this Act.

18          “(m) DISCRETION REGARDING USE OF AUTHORIZA-  
19          TION.—Nothing in this section provides the Secretary any  
20          authority to require any person to carry out any activity  
21          that becomes lawful pursuant to an authorization under  
22          this section, and no person is required to inform the Sec-  
23          retary that the person will not be carrying out such activ-  
24          ity, except that a manufacturer of a sole-source unap-  
25          proved product authorized for emergency use shall notify

1 the Secretary within a reasonable period of time after the  
2 issuance by the Secretary of such authorization if such  
3 manufacturer does not intend to carry out an activity or  
4 activities under the authorization. This section does not  
5 have any legal effect on a person who does not carry out  
6 any activity for which an authorization under this section  
7 is issued, or who carries out such an activity pursuant to  
8 other provisions of this Act or section 351 of the Public  
9 Health Service Act.

10 “(n) ENFORCEMENT.—A person who carries out an  
11 activity pursuant to an authorization under this section,  
12 but who fails to comply with applicable conditions under  
13 subsection (e), is with respect to that act of noncompliance  
14 subject to the provisions of law specified in subsection (a)  
15 and to the enforcement of such provisions under section  
16 301.”.

17 **SEC. 5. REPORTS REGARDING AUTHORITIES UNDER THIS**  
18 **ACT.**

19 (a) SECRETARY OF HEALTH AND HUMAN SERV-  
20 ICES.—

21 (1) ANNUAL REPORTS ON PARTICULAR EXER-  
22 CISES OF AUTHORITY.—

23 (A) RELEVANT AUTHORITIES.—The Sec-  
24 retary of Health and Human Services (referred  
25 to in this subsection as the “Secretary”) shall



1 submit reports in accordance with subpara-  
2 graph (B) regarding the exercise of authority  
3 under the following provisions of law:

4 (i) With respect to section 319F–1 of  
5 the Public Health Service Act (as added by  
6 section 2 of this Act):

7 (I) Subsection (b)(1) (relating to  
8 increased simplified acquisition  
9 threshold).

10 (II) Subsection (b)(2) (relating to  
11 procedures other than full and open  
12 competition).

13 (III) Subsection (c) (relating to  
14 expedited peer review procedures).

15 (ii) With respect to section 319F–2 of  
16 the Public Health Service Act (as added by  
17 section 3 of this Act):

18 (I) Subsection (c)(7)(C)(iii) (re-  
19 lating to simplified acquisition proce-  
20 dures).

21 (II) Subsection (c)(7)(C)(iv) (re-  
22 lating to procedures other than full  
23 and open competition).

1 (III) Subsection (c)(7)(C)(v) (re-  
2 lating to premium provision in mul-  
3 tiple-award contracts).

4 (iii) With respect to section 564 of the  
5 Federal Food, Drug, and Cosmetic Act (as  
6 added by section 4 of this Act):

7 (I) Subsection (a)(1) (relating to  
8 emergency uses of certain drugs and  
9 devices).

10 (II) Subsection (b)(1) (relating to  
11 a declaration of an emergency).

12 (III) Subsection (e) (relating to  
13 conditions on authorization).

14 (B) CONTENTS OF REPORTS.—The Sec-  
15 retary shall annually submit to the designated  
16 congressional committees a report that  
17 summarizes—

18 (i) the particular actions that were  
19 taken under the authorities specified in  
20 subparagraph (A), including, as applicable,  
21 the identification of the threat agent,  
22 emergency, or the biomedical counter-  
23 measure with respect to which the author-  
24 ity was used;

1                   (ii) the reasons underlying the deci-  
2                   sion to use such authorities, including, as  
3                   applicable, the options that were consid-  
4                   ered and rejected with respect to the use of  
5                   such authorities;

6                   (iii) the identification of each person  
7                   or entity that received, or was considered  
8                   and rejected for, grants, cooperative agree-  
9                   ments, or contracts pursuant to the use of  
10                  such authorities; and

11                  (iv) whether, with respect to each pro-  
12                  curement that is approved by the President  
13                  under section 319F–2(c)(6) of the Public  
14                  Health Service Act (as added by section 3  
15                  of this Act), a contract was entered into  
16                  within one year after such approval by the  
17                  President.

18                  (2) ANNUAL SUMMARIES REGARDING CERTAIN  
19                  ACTIVITY.—The Secretary shall annually submit to  
20                  the designated congressional committees a report  
21                  that summarizes the activity undertaken pursuant to  
22                  the following authorities under section 319F–1 of  
23                  the Public Health Service Act (as added by section  
24                  2 of this Act):

1 (A) Subsection (b)(3) (relating to in-  
2 creased micropurchase threshold).

3 (B) Subsection (d) (relating to authority  
4 for personal services contracts).

5 (C) Subsection (e) (relating to streamlined  
6 personnel authority).

7 With respect to subparagraph (B), the report shall  
8 include a provision specifying, for the one-year pe-  
9 riod for which the report is submitted, the number  
10 of persons who were paid amounts greater than  
11 \$100,000 and the number of persons who were paid  
12 amounts between \$50,000 and \$100,000.

13 (b) NATIONAL ACADEMY OF SCIENCES REVIEW.—

14 (1) IN GENERAL.—Not later than four years  
15 after the date of the enactment of this Act, the Sec-  
16 retary of Health and Human Services shall request  
17 the National Academy of Sciences to enter into an  
18 agreement for a review of the biomedical counter-  
19 measure research and development authorities estab-  
20 lished in this Act to determine whether and to what  
21 extent activities undertaken pursuant to such au-  
22 thorities have enhanced the development of bio-  
23 medical countermeasures affecting national security,  
24 and to recommend any legislative or administrative  
25 changes necessary to improve the ability of the Sec-

1       retary to carry out these activities in the future. The  
2       Secretary shall ensure that the results of the study  
3       are submitted to the designated congressional com-  
4       mittees not later than five years after such date of  
5       enactment.

6               (2) CERTAIN CONTENTS.—The report under  
7       paragraph (1) shall include—

8                       (A) a summary of the most recent analysis  
9                       by the Department of Homeland Security and  
10                      the intelligence community of the domestic  
11                      threat from chemical, biological, radiological,  
12                      and nuclear agents;

13                     (B) the Academy’s assessment of the cur-  
14                     rent availability of countermeasures to address  
15                     such threats;

16                     (C) the Academy’s assessment of the ex-  
17                     tent to which programs and activities under this  
18                     Act will reduce any gap between the threat and  
19                     the availability of countermeasures to an ac-  
20                     ceptable level of risk; and

21                     (D)(i) the Academy’s assessment of threats  
22                     to national security that are posed by tech-  
23                     nology that will enable, during the 10-year pe-  
24                     riod beginning on the date of the enactment of  
25                     this Act, the development of antibiotic resistant,

1 mutated, or bioengineered strains of biological  
2 agents; and

3 (ii) recommendations on short-term and  
4 long-term governmental strategies for address-  
5 ing such threats, including recommendations for  
6 Federal policies regarding research priorities,  
7 the development of countermeasures, and in-  
8 vestments in technology.

9 (c) GENERAL ACCOUNTING OFFICE REVIEW.—Four  
10 years after the date of the enactment of this Act, the  
11 Comptroller General of the United States shall initiate a  
12 study—

13 (1)(A) to review the Secretary of Health and  
14 Human Services' utilization of the authorities grant-  
15 ed under this Act with respect to simplified acquisi-  
16 tion procedures, procedures other than full and open  
17 competition, increased micropurchase thresholds,  
18 personal services contracts, streamlined personnel  
19 authority, and the purchase of security counter-  
20 measures under the special reserve fund; and

21 (B) to recommend any legislative or administra-  
22 tive changes necessary to improve the utilization or  
23 effectiveness of such authorities in the future;

1           (2)(A) to review the internal controls instituted  
2       by such Secretary with respect to such authorities,  
3       where required by this Act; and

4           (B) to recommend any legislative or administra-  
5       tive changes necessary to improve the effectiveness  
6       of such controls; and

7           (3)(A) to review such Secretary's utilization of  
8       the authority granted under this Act to authorize an  
9       emergency use of a biomedical countermeasure, in-  
10      cluding the means by which the Secretary deter-  
11      mines whether and under what conditions any such  
12      authorizations should be granted and the benefits  
13      and adverse impacts, if any, resulting from the use  
14      of such authority; and

15          (B) to recommend any legislative or administra-  
16      tive changes necessary to improve the utilization or  
17      effectiveness of such authority and to enhance pro-  
18      tection of the public health.

19 The results of the study shall be submitted to the des-  
20 ignated congressional committees not later than five years  
21 after the date of the enactment of this Act.

22       (d) REPORT REGARDING BARRIERS TO PROCURE-  
23      MENT OF SECURITY COUNTERMEASURES.—

24           (1) BIOCONTAINMENT FACILITIES.—Not later  
25      than 120 days after the date of the enactment of

1       this Act, the Secretary of Homeland Security and  
2       the Secretary of Health and Human Services shall  
3       jointly report to the designated congressional com-  
4       mittees whether there is a lack of adequate large-  
5       scale biocontainment facilities necessary for the test-  
6       ing of security countermeasures in accordance with  
7       Food and Drug Administration requirements.

8               (2) ADDITIONAL BARRIERS.—Not later than  
9       one year after the date of enactment of this Act,  
10      such Secretaries shall jointly report to the des-  
11      ignated congressional committees any other potential  
12      barriers to the procurement of security counter-  
13      measures that have not been addressed by this Act.

14      (e) STATUS OF PROGRAM FOR CHEMICAL TER-  
15      RORISM PREPAREDNESS.—Not later than 270 days after  
16      the date of the enactment of this Act, the Secretary of  
17      Homeland Security shall submit to the designated con-  
18      gressional committees a report describing the status of the  
19      program carried out by the Secretary to enhance the pre-  
20      paredness of the United States to respond to terrorist at-  
21      tacks involving chemical agents.

22      (f) DESIGNATED CONGRESSIONAL COMMITTEES.—  
23      For purposes of this section, the term “designated con-  
24      gressional committees” means the following committees of  
25      the Congress:



1           (1) In the House of Representatives: the Com-  
2       mittee on Energy and Commerce, the Committee on  
3       Appropriations, the Committee on Government Re-  
4       form, and the Select Committee on Homeland Secu-  
5       rity (or any successor to the Select Committee).

6           (2) In the Senate: the Committee on Health,  
7       Education, Labor, and Pensions, the Committee on  
8       Appropriations, and the Committee on Government  
9       Affairs.

10 **SEC. 6. OUTREACH.**

11       The Secretary of Health and Human Services shall  
12       develop outreach measures to ensure to the extent prac-  
13       ticable that diverse institutions, including Historically  
14       Black Colleges and Universities and those serving large  
15       proportions of Hispanics, Native Americans, Asian-Pacific  
16       Americans, or other underrepresented populations, are  
17       meaningfully aware of available research and development  
18       grants, contracts, cooperative agreements, and procure-  
19       ments conducted under sections 2 and 3 of this Act.

20 **SEC. 7. RECOMMENDATION FOR EXPORT CONTROLS ON**  
21 **CERTAIN BIOMEDICAL COUNTERMEASURES.**

22       Upon the award of any grant, contract, or cooperative  
23       agreement under section 2 or 3 of this Act for the re-  
24       search, development, or procurement of a qualified coun-  
25       termeasure or a security countermeasure (as those terms

1 are defined in this Act), the Secretary of Health and  
2 Human Services shall, in consultation with the heads of  
3 other appropriate Federal agencies, determine whether the  
4 countermeasure involved in such grant, contract, or coop-  
5 erative agreement is subject to existing export-related con-  
6 trols and, if not, may make a recommendation to the ap-  
7 propriate Federal agency or agencies that such counter-  
8 measure should be included on the list of controlled items  
9 subject to such controls.

10 **SEC. 8. ENSURING COORDINATION, COOPERATION AND**  
11 **THE ELIMINATION OF UNNECESSARY DUPLI-**  
12 **CATION IN PROGRAMS DESIGNED TO PRO-**  
13 **TECT THE HOMELAND FROM BIOLOGICAL,**  
14 **CHEMICAL, RADIOLOGICAL, AND NUCLEAR**  
15 **AGENTS.**

16 (a) ENSURING COORDINATION OF PROGRAMS.—The  
17 Secretary of Health and Human Services, the Secretary  
18 of Homeland Security, and the Secretary of Defense shall  
19 ensure that the activities of their respective Departments  
20 coordinate, complement, and do not unnecessarily dupli-  
21 cate programs to identify potential domestic threats from  
22 biological, chemical, radiological or nuclear agents, detect  
23 domestic incidents involving such agents, analyze such in-  
24 cidents, and develop necessary countermeasures. The  
25 aforementioned Secretaries shall further ensure that infor-

1 mation and technology possessed by the Departments rel-  
2 evant to these activities are shared with the other Depart-  
3 ments.

4 (b) DESIGNATION OF AGENCY COORDINATION OFFI-  
5 CER.—The Secretary of Health and Human Services, the  
6 Secretary of Homeland Security, and the Secretary of De-  
7 fense shall each designate an officer or employee of their  
8 respective Departments who shall coordinate, through reg-  
9 ular meetings and communications, with the other afore-  
10 mentioned Departments such programs and activities car-  
11 ried out by their Departments.

Passed the House of Representatives July 16, 2003.

Attest:

*Clerk.*